UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 18, 1984

OFFICE OF
THE ADMINISTRATOR

Mr. William D. Ruckelshaus
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Ruckelshaus:

On June 7, 1984, the Environmental Health Committee (EHC) of the Science Advisory Board reviewed a Draft Health Assessment Document (HAD) for Dichloromethane (DCM; Methylene Chloride) dated December 1983 and prepared by the Agency's Office of Research and Development (ORD). The Report reflects in part some data from a study by the National Coffee Association of the U.S.A., Inc., which were neither peer-reviewed nor published in an edited scientific journal. Due to these two factors, the EHC recommends that EPA delete reference to this study from the HAD. ORD staff are to be complimented, however, for their awareness of the data and its implications. Otherwise, the draft fairly reflects the available scientific literature.

With respect to the conclusions reached, the EHC passed the following resolution:

> Motion: The unit risk sections of the Dichloromethane Health Assessment Document should be removed, because of the inadequate data base for judging the carcinogenicity of this compound. While the (1) issues of classification of carcinogenic compounds and (2) whether or not to calculate unit risks by Carcinogen Assessment Group (CAG) procedures, were discussed generally at this meeting, this motion is specific to DCM and not to other chemicals. In the case of DCM, CAG has relied primarily on one animal study of questionable value. The use of CAG procedures to calculate unit risk for DCM at this point in time is inappropriate and should not be part of this document.

In explanation of this motion, the EHC points to the study report of the National Academy of Sciences (NAS) Committee on the Institutional Means for Assessment of Risks to Public Health. The NAS Committee clearly distinguished the concepts of risk assessment and risk management and described how risk assessment itself necessarily contains a component of scientific assumption or inference. The NAS Committee also described how scientists can contribute to the topic of inference, however, and so it belongs in the domain of risk assessment as a scientific activity. The

NAS Committee also described the need to have guidelines for inference. The case of DCM further emphasizes the need for such guidelines.

Due to (1) the biology of the tumors seen in one bioassay with DCM, which some members thought were poorly characterized, and which may well be manifestations of virus infections, (2) an apparent lack of reproducibility in the incidence of the same tumors in the same species, (3) metabolic properties of DCM, and (4) mechanistic considerations, the EHC finds that the calculation of a unit risk for DCM lacks a scientific basis. ORD staff thought that they detected a signal in the data that they could not ignore; the EHC disagreed with ORD staff regarding the significance of the signal. Whereas ORD staff found the data for DCM limited but adequate for unit risk calculations, the EHC finds that these data are limited and inadequate. For the Committee to take a formal vote is unusual and reflects the degree of its concern over this issue.

The resolution does not mean that the Agency cannot elsewhere apply unit risk methods and examine their implications. Rather, it reflects that such policy analysis for DCM clearly belongs in the area of risk management and should not be part of a scientific document. As a matter of risk management, EPA can calculate a unit risk, compare this risk to epidemiologic data, or estimate the probability of causation. Indeed, some members of the EHC strongly urge the Agency to do so with DCM. In their discussion some members also suggested that some quantitative measure of CAG's confidence in the data accompany unit risk estimates. The majority of the EHC thinks that to place the unit risk calculations for DCM within an HAD creates confusion about adequacy of the data.

In other regards the Report concludes:

(1) That "adverse toxicologic effects (other than carcinogenicity and mutagenicity) in humans are unlikely to occur at ambient air and water levels found or in the general environment or even at higher levels sometimes observed in urban areas." The EHC concurs with this conclusion but advises that the general tone of the Summary and Report does not reflect this statement.

(2) That "the weight of the evidence shows that DCM is capable of causing gene mutations and has the potential to cause such effects in exposed human cells." The EHC concurs with the essence of the statement but advises that the language of the HAD is ambiguous, particularly in regard to qualifiers such as "weak" mutagen. The EHC recommends that the Agency tentatively use reference language developed by some scientifically recognized body, such as the NAS or the International Agency for Cancer Research (IARC), until EPA can develop a classification to meet its specific needs.

(3) That DCM falls into Class 3 (insufficient evidence) according to IARC criteria for carcinogens. The EHC unanimously agreed with this conclusion but advises that EPA should not attempt to develop a range, spectrum, or subclassification of IARC Class 3 chemicals without first setting out general criteria for these new definitions.

Detailed technical comments will be communicated directly to ORD. We appreciate the opportunity to review this document and request that the Agency formally respond to our letter.

Sincerely,

Herschel E. Griffin, Chairman
Environmental Health Committee

Norton Nelson, Chairman
Executive Committee

cc: Alvin L. Alm (A-101)
Joseph A. Cannon (ANR-443)
Bernard D. Goldstein (RD-672)
Terry F. Yosie (A-101)